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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,623	07/15/2004	Philippe Moussou	C 2319 PCT/US	2222
23657 7590 11/28/2007 COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			EXAMINER MI, QIUWEN	
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			1655	
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			11/28/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,623	<b>Applicant(s)</b> MOUSSOU ET AL.	
	<b>Examiner</b> Qiuwen Mi	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 41, 43-48, 53, 54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) 57-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41, 43-48, 53, 54, 56, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 10/23/07 is acknowledged.

Any rejection not reiterated is hereby withdrawn.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2007 has been entered.

### **Election/Restrictions**

Applicant's election with traverse of claims 41, 43-48, 53, 54, 56, 61, and 62 in the reply filed on 4/3/2007 is maintained. The traversal is on the ground(s) that Examiner failed to provide examples how different invention groups are distinct and different. This is not found persuasive because in a 371 case, as long as there is no special technical feature in the application, which was stated clearly in the previous office action, accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1., and therefore lack of unity of invention exists.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's argument regarding election of species is found convincing, therefore the requirement for the election of species is hereby withdrawn.

### **Claims Pending**

Applicant has cancelled claims 1-40, 42, 49-52, and 55. Claims 41, 43-48, 53, 54, and 56-62 are pending. Claims 57-60 are withdrawn. Claims 41, 43-48, 53, 54, 56, 61, and 62 are examined on the merits.

### **Claim Rejection 112, 1<sup>st</sup>**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41, 43-48, 53, 54, 56, 61, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a process of producing a cosmetic and/or pharmaceutical active component, comprising (a) providing a fermentation broth comprising a plant component selected from the group consisting of rice plant constituent, rice plant extracts and mixtures thereof; (b) inoculating the fermentation broth with a mixture of microorganisms comprising at least one *Lactobacillus*, at least one *Lactococcus*, at least one *Leuconostoc* and at least one yeast"; (c) fermenting the microorganism-containing fermentation broth to produce an active component.

To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the invention recite the limitation “providing a fermentation broth” and “inoculating the fermentation broth” assumes the existence of a fermentation broth with a mixture of the claim-designated microorganisms, namely *Lactobacillus*, *Lactococcus* and *Leuconostoc*, and at least one yeast, but no description regarding what ingredients are contained therein the “fermentation broth comprising a plant component selected from the group consisting of rice plant constituents, rice plant extracts and mixture thereof” is being disclosed in the specification. In addition, it is not clear exactly what “active component” Applicant is referring to, and there is no chemical name or structure being disclosed in the specification. Accordingly, in the absence of sufficient recitation of the components in the fermentation broth, the specification does not provide adequate written description of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page

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1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

### **Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 43-48, 53, 54, 56, 61, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The metes and bounds of claims 41 and 56, as drafted in their entirety, are rendered vague and indefinite, especially with regard to the recitation of “(a)” **providing a fermentation broth** comprising a plant component selected from the group consisting of rice plant constituent, rice plant extracts and mixtures thereof; (b) **inoculating the fermentation broth** with a mixture of microorganisms comprising at least one *Lactobacillus*, at least one *Lactococcus*, at least one *Leuconostoc* and at least one yeast” for the following reasons: The recitation of the limitation “providing a fermentation broth” and “inoculating the fermentation broth” assumes the existence of a fermentation broth with a mixture of the claim-designated microorganisms, namely *Lactobacillus*, *Lactococcus* and *Leuconostoc*, and at least one yeast. Giving the foregoing, it is uncertain as to what are the ingredients contained therein the “fermentation broth comprising a plant component selected from the group consisting of rice plant constituents, rice plant extracts and mixture thereof” as recited in the claim-designated process step of “(a)”. The lack of clarity renders the claims very ambiguous.

The metes and bounds of claim 41 and 56 are further rendered vague and indefinite by term “extract” because this term, in and of itself, does not adequately delineate its metes and bounds. An “extract” is only defined by the process of its preparation. Such product-by-process claims are intended to define products which are otherwise difficult to define and/or distinguish from the prior art except by the process of making. Since any given biological source contains thousands of extractable compounds, each with its own particular extraction properties, the nature of resulting “extract” will depend on the conditions of the extraction and solvent used. For example, at what temperature is the extraction performed; is the extract of a biological source with one of various distinct solvents has a profound impact on the final product with respect to

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the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the “extract” to provide the desired functional effects(s) claimed and/or disclosed. Since the “extract” itself is clearly essential to the instantly claimed invention, the steps(s) by which the claimed “extract” is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Claims 41 and 56 recite the limitation “the microorganism-containing fermentation broth”. There is a lack of clear antecedent basis for this limitation in the claims. Perhaps, Applicant may overcome the rejection by adding to obtain a microorganism-containing fermentation broth after “yeast” in each of the claims.

The metes and bounds of claim 45 are rendered vague and indefinite, as drafted in its entirety, because it is unclear as to what “fermentation broth is adjusted to a pH of from 4.5 to 8.5 prior to fermentation”, since the recitation of claim 41 appears to read on a process of inoculating a fermentation broth comprising rice plant constituents, or rice plant extracts, and/or mixtures thereof with a mixture of claim-designated microorganisms and at least one yeast and fermenting the microorganism-containing fermentation broth to produce an active component. The lack of clarity renders the claims very confusing and ambiguous.

Claim 54 recites the limitation “the fermented broth” in line 2. There is insufficient antecedent basis for this limitation in the claim.



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Claim 56 recites the limitation “the fermented broth” in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claims 61 and 62 recite the limitation “The product” in line 1. There is insufficient antecedent basis for this limitation in the claims. Applicant may overcome the rejection by replacing “The” with A.

Claims 41 and 56 recite “rice plant extract”, and the metes and bound of those claims are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical and animal matter noted in this application. Applicant may overcome the rejection by placing the genus-species name of “X” in parentheses after the term (s) “X”. Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 43-48, 53, 54, 56, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawaki et al (US 2004/0052759), in view of Uno et al (US 2001/0041203) and Miyazaki et al (US 7,090,875), further in view of Klaenhammer et al (US 5,618,723).

This is a new rejection.

Sawaki et al teach cosmetics containing an active component comprising lactic acid bacteria fermented rice obtained by fermenting rice with lactic acid bacteria (see Abstract). Sawaki et al also teach that lactic acid bacteria to be used for fermentation of such raw rice include, for example, *Lactobacillus*, and *Streptococcus* (the same as *lactococci*, see Klaenhammer et al (US 5,618,723), col 10, line 1-5) *faecalis* etc [0016]). Sawaki et al further teach that the cosmetics can be obtained, which are excellent in emulsion stability and biological safety, have a good feeling when using and after using and further have a total beautifying effect of cosmetic treatment including an improving effect on hair texture, and brightening and caring effects on the skin (see Abstract).

Sawaki et al do not teach the claimed pH, pretreatment, temperature, and separation method, and Sawaki et al do not teach that *Leuconostoc*, and yeast are used in fermenting rice.

Uno et al teach adding water and yeast to rice, heating at 90°C for 30 min (pretreatment), fermenting at 20°C for 2 days, and then being filtered [0129; 0130]. Uno et al also teach that the invention being used in cosmetics [0076; 0077; 0079; 0080]. Uno et al also teach that liquefying process (pretreatment) can facilitate fibrous hydrolase activity and ferulic acid esterase activity, and contribute to decomposition of fibers in cereals and liberation of ferulic acid [0071] which can be further used in cosmetics [0076].

Miyazaki et al teach a fermented product prepared by microorganisms such as lactobacillus, lactococcus, and leuconostoc, or by several kinds of strains in combination at pH preferably 5.0-6.0 (col 5, lines 50-55). Miyazaki et al also teach that the fermented product can improve dry, roughed, wrinkled, or loosened skin and prevent the skin from aging (col 2, lines 47-55).

Klaenhammer et al teach that bacterial used in the fermentation of dough formed from cereals (e.g., wheat, rye, rice, oats, barley, and corn) include yeasts such as *Saccharomyces cerevisiae* and *Candida utilis*, and lactic acid bacterial of genera *Lactobacillus*, *Lactococcus*, *Leuconostoc* etc (col 9, lines 42-48).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the pretreatment, and the separation (filtering) method of Uno and the pH of Miyazaki et al in Sawaki et al for the following reasons.

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It is clear from Uno et al that liquefying process (pretreatment) can facilitate fibrous hydrolase activity and ferulic acid esterase activity, and contribute to decomposition of fibers in cereals and liberation of ferulic acid [0071] which can be further used in cosmetics [0076], therefore it is obvious for one of ordinary skill in the art at the time the invention was made to follow the procedure of Uno et al in Sawaki et al to make the fermented rice extract so that the rice fermentation product in Sawaki et al can be used in cosmetics.

It is further clear from Miyazaki et al that keeping the fermented product at pH 5-6 suits for cosmetic skin application in cosmetic products, therefore it is obvious for one of ordinary skill in the art at the time the invention was made to use the pH of Miyazaki et al in the fermented product in Sawaki et al to achieve the antiaging effect in cosmetics.

Since all the inventions of Sawaki et al, Uno et al and Miyazaki et al yielded beneficial results in the cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications.

It would be obvious to combine lactobacillus, lactococcus, leuconostoc, and yeast together to enhance the fermenting effect, as Klaenhammer et al teach each of them individually as examples in the fermentation preparations. Since Klaenhammer et al only teach fermentation of rice etc include yeasts such as *Saccharomyces cerevisiae* and *Candida utilis*; and lactic acid bacteria of genera *Lactobacillus*, *Lactoccus*, *Pediococcus* and *Leuconostoc*, thus choosing from a finite number of predictable solutions (choosing from three genus out of four) would have been obvious because a person of ordinary skill has good reason to pursue the known options with his

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or her technical grasps. If this leads to the anticipated success, it is likely the product not of innovation, but of ordinary skill and common sense.

Regarding determining the pH of the fermented product, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, depending upon the types and the amounts of the bacteria used for fermentation.

From the teachings of the references, it is apparent that one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

  
MICHELE FLOOD  
PRIMARY EXAMINER